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K001326

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510(k) Summary

April 25, 2000

Contact: Kevin Schou, BCO, Scientific and Technical Director

Device Name: Natural-Iris™ Pre-Pigmented Corneal Button

Common Name: Iris Button or Corneal Button

Classification: Artificial Eye Component (per 21 CFR section 886.3130)
Medical Specialty – Ophthalmic
Product Code – HQH Device Class – 1

Equivalent Product: Ocularist fabricated clear, poly-methylmethacrylate (PMMA) corneal buttons or commercially available (PMMA) clear, corneal buttons from Oculo-Plastik, Inc., 200 Sauve' West, Montreal Quebec, Canada H3L 1Y9, Tel: (514) 381-3292, Fax: (514) 381-1164.

Device Description: A clear, poly-methylmethacrylate iris button that contains a computer generated pigmented iris image. A component used in the fabrication of custom made artificial eyes.

Intended Use: "Natural-Iris™ pre-pigmented corneal buttons are intended to be used by professional Ocularists in the fabrication of custom made, poly-methacrylate ocular prostheses. When a PMMA ocular prosthesis is completed, the Natural-Iris™ corneal button should be completely encapsulated by the acrylic forming the prosthesis. If, in the process of polishing or "cutting down" a prosthesis, the polyester substrate (i.e. white posterior) becomes exposed, treat it the same as you would when using black vinyl painting disks (i.e. repair or discard the prosthesis)."

Testing: Ocular Concepts has provided several samples of the pre-pigmented iris buttons to Ocularists for testing, processing, and evaluation. These non-clinical tests indicate the device performs identical to the existing predicate devices. The pre-pigmented buttons were processed using the Carver press, microwave, water bath and dry oven processing methods.

The follow table illustrates the similarities and differences of the Ocular Concepts Pre-Pigmented Corneal Button with existing, predicate devices:

	Existing Iris Buttons	Natural-Iris™ Button
Indications for Use	Custom Artificial Eyes	same
Processing Methods	Carver press, microwave, water bath, dry oven.	same
Materials	Poly-methylmethacrylate (PMMA) button	same
Pigments Used	Variety of oil based, water based, and dry pigments.	Computer generated image created using Cyan-Phtalocyannine Blue (PB15:3), Magenta-Quinacridone (P122), Yellow-Bishmuch Vanadate (PY184), and Carbon Black (PK7) pigments.
Coloring Process	Hand painted button.	Graphic arts image glued to button.
Sterility	nonsterile	same
Target Population	Patients with eye loss	same
Anatomical sites	Artificial eye	same
Human Factors	Natural appearance	same
Where Used	In office of professional Ocularists	same

Summary: The device uses the same material found in the predicate devices. The modification is the addition of a pigmented image to the surface of the button. Ocularists use the pre-pigmented button exactly like the predicate devices. No change in processing methods is required.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 13 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ocular Concepts LLC
c/o Mr. Kevin Schou
Director
4035 SW Mercantile Drive
Suite 208
Portland, Oregon 97035-2591

Re: K001326
Trade Name: Natural-Iris Pre-Pigmented Corneal Button
Regulatory Class: Class I
Product Code: NCK
Dated: April 25, 2000
Received: April 26, 2000

Dear Mr. Schou:

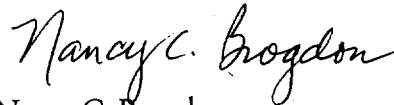
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "Nancy C. Brogdon".


Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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510(k) Number: K001326

Statement of Indications for Use

"Natural-Iris™ pre-pigmented corneal buttons are intended to be used by professional Ocularists in the fabrication of custom made, poly-methacrylate ocular prostheses. When a PMMA ocular prosthesis is completed, the Natural-Iris™ corneal button should be completely encapsulated by the acrylic forming the prosthesis. If, in the process of polishing or "cutting down" a prosthesis, the polyester substrate (i.e. white posterior) becomes exposed, treat it the same as you would when using black vinyl painting disks (i.e. repair or discard the prosthesis)."


(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K001326

Prescription Use ☒
(Per 21 CFR 801.109)